# Fundamentals of Medicare Patient Safety Surveillance: Intent, Relevance, and Transparency

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## Abstract

The Medicare Patient Safety Monitoring System (MPSMS) is a national surveillance project aimed at identifying the rates of specific adverse events within the Medicare population. Created under the auspices of the Department of Health and Human Services' Patient Safety Task Force, this surveillance system identifies adverse events from randomly selected inpatient Medicare discharges and administrative data. This system is immense in scope and provides national rates of adverse events by employing explicit review criteria for all patient safety topics. The MPSMS explicit review is a patient-centered process focusing on patient harm rather than provider or system error, and has the following features: normalized inter-rater reliability; lower cost-per-chart reviewed than the traditional clinical expert-based implicit review; and the potential for comparative analysis across time and health care systems. A limitation to our approach is the reliance on administrative data to complete any post-discharge surveillance required. This paper explores the precepts behind the MPSMS review process. Three principles—intent, relevance, and transparency—describe the conceptual underpinnings for our approach.

## Introduction

Patient safety, while not a new topic, recently has experienced a renewed sense of urgency in public health discourse. This urgency is, in part, precipitated by the confluence of market pressures to demonstrate value in a health care system increasing in technological sophistication yet lacking the commensurate capacity to measure and, in turn, reduce the rate of fundamental defects as measured by patient harm. This point was brought into sharp focus in the 2000 Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System.*[1] The IOM reported that between 44,000 and 98,000 patients die each year in the United States, as a result of their interaction with health care delivery systems. Two byproducts of that report are invigorated programs to measure and improve the safety of those systems. A surveillance system, the MPSMS, is one such program and has the goal of measuring the rate of specific inpatient adverse events within the Medicare population.

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# Methods

## Sampling strategy and record abstraction

The hospital records from an annual random national sampling of more than 40,000 Medicare inpatient fee-for-service discharges are sent to two Clinical Data Abstraction Centers (CDAC). At the CDACs, trained abstractors processed each clinical chart by recording predefined chart data. Abstractor training for this process includes didactic instruction and documentation regarding concept definitions; rules of precedence regarding where in the chart predefined information should be extracted; and key terminology and synonyms.

Determination of inter-rater reliability and accuracy is part of the MPSMS Internal Quality Control (IQC). As part of that process, every month 40 randomly selected abstracted charts are exchanged between the two CDACs. These charts are then re-abstracted and the aggregated results are listed (Table 1). Adjudication of results in which there is a discrepancy between abstracts is overseen by members of the MPSMS contractor, Qualidigm, and the Connecticut Quality Improvement Organization (QIO). The results of the adjudication are then incorporated into the CDAC abstractor training and instruction documentation.

**Table 1: Aggregated MPSMS reliability**

| | |
|---|---|
| Completeness measure | 99.5% |
| Number of cases produced | 40,620 |
| Number of cases sampled | 480 |
| Inter-rater reliability | 96.66% |
| Overall accuracy | 98.03% |

For the purposes of this report, the completeness measure is based on the actual case data and is not a measure of validated responses. This measure provides information about the average completeness of a case in the IQC sample. The denominator includes all variables with an abstracted response for all original and re-abstracted cases. The numerator includes all variables with a response excluding the one, unable to determine (UTD). The percent complete is the aggregate average of all cases.

Inter-rater reliability is calculated as the raw agreement rate between the original abstractor and the re-abstractor. For example, if the module contains 100 data elements and the abstractors agree on 90 of them, the reliability score would be 90 percent. The inter-rater reliability is the aggregate agreement rate across all data elements in all cases in the IQC sample.

Accuracy is calculated as the raw agreement rate of both the original abstractor and the re-abstractor with the adjudicated gold standard data. The overall accuracy is the aggregate agreement rate across all data elements in all cases in the IQC sample.

The final data source for the MPSMS is the CMS administrative data set for each of the randomly selected inpatient records. This data set contains all the information from beneficiary Medicare Part A claims, Medicare Part B claims, and the beneficiary master file. These files contain hospital admission and professional component procedure and diagnosis codes. The beneficiary master file includes socio-demographic information. The value of the administrative data set is that it can be used to complement information garnered for an individual inpatient episode of care, such as 30-day postoperative mortality, readmission, or return to the operating room. This is very important given that the MPSMS has no capacity to obtain additional or related records for an individual case beyond the initial, randomly selected hospital chart.

## Definition of variables and explicit criteria

An adverse event is defined as an unintended harm, injury, or loss that is more likely associated with a patient's interaction with the health care delivery system than from an attendant disease process. The MPSMS identifies adverse events in discrete clinical topics only and there is no attempt to identify adverse events beyond the list of MPSMS topics. An MPSMS topic algorithm, algorithm abstraction instructions, and algorithm definitions wholly define an adverse event in the MPSMS. The first year of abstraction involved data collection and analysis for adverse events in the following topics: bloodstream infections; central venous catheters (CVC); total hip and total knee replacement; postoperative pneumonia, postoperative venous thromboembolic events; postoperative urinary tract infection; and ventilator associated pneumonia. All chart abstraction is performed at CDACs and all data analysis is performed at the Connecticut Medicare Quality Improvement Organization, Qualidigm.

Once proposed, a topic is vetted through a process that first includes providing our entire technical expert panel (TEP) with a thorough literature review. As we compile and share the literature review, both the strengths and weaknesses of the potential MPSMS topic are discussed with the TEP and other national experts. Especially important are the opinions of CMS's federal agency TEP partners, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Agency for Healthcare Research and Quality (AHRQ), and Department of Veterans Affairs (VA). Throughout the process, practical considerations such as the estimated frequency of exposures in the Medicare fee-for-service inpatient population and the richness of event descriptors (or proxies) being documented in the record are considered. If a topic meets all reasonable standards to this point, the MPSMS team at Qualidigm then designs preliminary technical specifications with input from selected TEP subject matter experts.

These preliminary technical specifications define each adverse event category; provide specifications of numerator(s) and denominator(s); list inclusion and exclusion criteria; and define data sources for each measure. Specifically, for each measure, the preliminary technical specification includes—

1. Exposure/adverse event (the name of the exposure/adverse event).

2. Description (a description of the exposure/adverse event measure).

3. Definition (a detailed definition of the exposure/adverse event measure).

4. Adverse event (a list of adverse events to be examined for each measure).

A list of critical definitions and synonyms is complied, concurrent with the algorithm design. The algorithm is then "alpha" tested with nurse reviewers to identify if explicit discriminators within the algorithm can be extracted from a sample. Detailed results and comments from this review are analyzed, and, if necessary, algorithm improvements exacted.

The results of alpha testing allow for refinement of the data collection tool, the tool instructions, and analysis algorithms. The "beta" test serves as the next level of testing. It is used to assess the validity and reliability of the data collection tool variables for each specific measure.

The beta test includes the following components:

- revisions to the measure algorithms;

- refinement of the data collection tool and instructions to improve accuracy, consistency and ease of abstraction;

- assessment of the reliability and validity of the abstractors and abstracted data elements; and

- completion of a test run of data processing and reporting methods.

Specifically, Beta testing involves—

- creating gold standard records;

- validating abstractors' work using gold standard records;

- testing abstractor-level reliability;

- assuring 95 percent inter-rater reliability; and

- performing clinical review for the measure exposures and associated adverse events.

Independent, practicing clinicians are employed for the last phase of beta testing, clinical review. The purpose of the MPSMS beta clinical review process is twofold:

1. To determine if practicing clinicians, using their clinical judgment and Qualidigm and CDAC abstractors, were able to identify the same patients as being exposed to a specific health care delivery process, and identify the same patients as experiencing specific adverse events associated with the exposures.

2. To assess the clinician reviewers' degree of certainty that the adverse events identified were associated with the exposure. This information will be used in the overall evaluation of the effectiveness of the MPSMS beta abstraction tool and algorithm in detecting health care exposures and associated adverse events.

Each topic module and any associated adverse event rate data are reviewed at least annually by the TEP.

## Confidentiality

MPSMS is a quality improvement project. Thus, information collected is protected by Federal law against disclosure in a form that identifies individuals or providers, and against discovery or subpoena in civil actions**.** This project also meets all the requirements of Health Insurance Portability and Accountability Act of 1996 (HIPAA).

## Discussion

The purpose of this paper is to present the philosophical underpinnings of the MPSMS as a new paradigm in patient safety monitoring. Beyond the uniqueness of this surveillance system, the MPSMS team recognized the inherent imperative that those who conduct patient safety surveillance thoroughly describe not only a study's methodology but also the thought processes that guided the methodology design and maintenance. Because results of national patient safety surveillance studies are used at all levels of health care services delivery, from public health policy to specific provider treatment decisions, a descriptive acknowledging the study gestalt has intrinsic value. To that end, it is best to first recognize that the MPSMS relies solely on retrospective review of written hospital records and insurance claims. In that regard, the MPSMS remains in the same category of patient safety surveillance as the AHRQ Patient Safety Indicators (PSI) and the Harvard Medical Practice Review in that there is no provision to acquire information beyond those two records.

Still, the MPSMS represents a new paradigm. Adverse event determinations, based on AHRQ Patient Safety Indicators, are exclusively derived from claims and are incapable of discriminating events by exploiting the clinical detail of the hospital chart not reflected in an insurance claim. Conversely, patient safety surveillance as performed in the Harvard medical practice study is limited by "moderate reliability of judgements about adverse events."[2] The Harvard approach employs structured implicit review instruments. Clinicians are "trained to review hospital medical records and give their opinion on the occurrence of adverse events and the quality of hospital care and its impact on patient outcomes,"[3] MPSMS the new surveillance paradigm, is designed by CMS to conduct an explicit review by extracting relevant data in both the clinical record and the administrative claims data set with a high degree of inter-rater reliability. A well-defined algorithm is then applied to that data to determine a rate of adverse events. As such, the MPSMS methods, algorithms, and definitions may

be employed to establish rates of adverse events by any entity with access to a large chart-based data source (e.g., hospitals, health plans, provider networks, and payers). Before any such employ, it is essential to understand the fundamental precepts behind our surveillance project design. For this, we find it most useful to describe the MPSMS relative to three coordinates or requirement planes: intent, relevance, and transparency.

## Intent

Intent answers the broader question: "For what purpose will the information be used?" To fully answer, it is best first to define how the MPSMS fits into the larger Centers for Medicare and Medicaid Services (CMS) Quality Improvement Program.

The MPSMS is administered through the Quality Improvement Group (QIG) in the Office of Clinical Standards and Quality (OCSQ) at CMS. The project goal contributes to a larger mission of accelerating the pace of health care quality improvement in the United States. In this context, the QIG subscribes to the principle explicitly stated in the 2003 IOM report on Patient Safety Data Standards "that patient safety is indistinguishable from the delivery of quality care."[4] Within that larger mission, the role of the MPSMS is only the measurement of adverse events. The project has no capacity to initiate interventions or affect change in the topics observed. That capacity is the work of other quality improvement projects within QIG. Specialization of MPSMS functionality to focus only on measurement significantly reduces the operational complexity.

The concept of patient safety is central to any discussion of the MPSMS. Webster's New World Dictionary defines safety as "the condition of being free from harm, injury, or loss." Thus, patient safety is the condition or act of freeing a patient from unintended harm, injury, or loss that is more likely associated with his/her interaction with the health care delivery system than from an attendant disease process.

In this definition, the operative words are "patient" and "harm."[4] Not addressed is the concept of error—and this is an important distinction. This focus on patient harm, with limited consideration of mitigating factors, is our definition of patient-centered: the well-being and the perspective of the patient remain the primary consideration. A patient-centered—as opposed to a provider-centered—approach is essential to our quality improvement efforts at CMS. By placing our focus on the protection of the patient, CMS engages a more achievable goal to safety design—fault tolerance. Fault tolerance is the capacity of a system, in this case a health care system, to gracefully recover from an unexpected failure before the typical consequence of that failure can adversely affect the desired result. As opposed to a provider-centered focus of error elimination, fault tolerance attempts to create systems that minimize or eliminate patient harm despite the introduction of errors. There is ample precedent for this approach. Fault tolerance is widely accepted by the broader safety community in other disciplines such as airline safety and computer network reliability. These areas recognize that the complete

elimination of error in human endeavor is not likely to succeed under any conditions. In *On Hierarchical Design of Computer Systems for Critical Applications,* Peter Gabriel Neumann states very clearly: "No system is guaranteed to work properly all the time…humans in the loop may add to the problem rather than improve it."[5] Patient-centered intent carries huge practical implications in the conduct of a health care surveillance system, one of the first and most notable of which is how MPSMS addresses the question of comorbid risk. Robust patient risk stratification is an important feature of systems designed to draw comparisons of provider performance. Risk stratification recognizes that medical outcomes are, in part, influenced by the comorbid attributes of the patients involved. But when the outcome studied is harm, the results are typically presented in such a way as to dissipate some provider culpability by establishing a relative ranking of error. The result is that patients with greater comorbid risk are considered less harmed (e.g., a pneumothorax subsequent to subclavian catheterization is not considered as egregious in the morbidly obese). This is inherently a provider-centered approach, ill-suited for a national surveillance system aimed only at estimating patient harm. While the MPSMS has no mandate or capacity to measure or publicly report provider rates of adverse events, our fiduciary responsibility toward public disclosure extends well into the CMS mission as a piece of the national public health infrastructure.

Part of the CMS public health mission has always been the intent to assure that the MPSMS remains applicable beyond a guide for quality improvement projects at CMS. Another goal has been our inclusion in the annual National Healthcare Quality Report. MPSMS modules may be applied by any entity with access to a large chart-based data source. Thus in 2005 the CMS will make available MPSMS modules to hospitals, provider networks, and health plans to aid in their internal estimation of adverse events.

## Relevance

The CMS fiduciary responsibility has direct implications on the topics considered in the MPSMS. As a federal agency, CMS must keep its patient safety policy consistent with the distinct public health mission of the Department of Health and Human Services (DHHS).

Unlike other adverse event surveillance projects, the MPSMS uses explicit chart review. This approach requires that the system maintain a discrete, well-defined list of surveillance topics. Compared with other patient safety projects that attempt to identify all adverse events in a given care episode,[2] the MPSMS only has the capacity to identify rates for select adverse events. For the purposes of an explicit review program, the MPSMS must address the question of which discrete topics to consider; in other words, which topics are relevant. Our current topics have largely been selected based on the prioritized list of patient safety topics compiled by the AHRQ, the DHHS agency charged with providing leadership in patient safety. The IOM, in its 2000 report, recommended that AHRQ identify and disseminate best patient safety practices.[1] The product of that recommendation is *Making Health Care Safer: A Critical Analysis of Patient*

*Safety Practices.*[6] Chapter 57 of that compendium provides a list of patient safety topics "ranked on a metric for potential impact." Table 2 lists the topics in which the MPSMS is currently collecting data (production), topics for which data collection began in July 2004 (pre-production), and the two topics undergoing criteria development (developmental).

**Table 2: MPSMS Topics**

| Production | Pre-production | Developmental |
|---|---|---|
| Bloodstream infections* | Adverse drug events ** | Hospital falls** |
| CVC* | Pressure ulcers* | Angiographic adverse events*** |
| Hip/knee replacement | Postoperative cardiac events* | Methicillin-resistant Staphylococcus aureus and Vancomycin-resistant Enterococcus* |
| Postoperative pneumonia | | |
| Postoperative DVT/PE* | | |
| Hospital acquired UTI** | | |
| Ventilator associated pneumonia** | | |

CVC = central venous catheter; DVT = deep vein thrombosis; PE = Pulmonary embolism; UTI = urinary tract infection
* Greatest impact and strength of evidence
** High impact and strength of evidence
*** Contrast-induced renal failure, an angiographic complication is rated as medium impact and strength of evidence.  The other angiographic complication being considered by the MPSMS, mechanical hemostatic adverse events was identified by the FDA as of emerging importance.

After independently rating patient safety topics for potential impact and the strength of evidence supporting a preventative intervention, AHRQ created a five-tier hierarchy—greatest, high, medium, low, and lowest impact. By heavily leveraging our work in those topics rated for greatest or high impact and strength of evidence, the MPSMS maintains a national public health relevance (see Table 2).

Beyond the conscious decision to assure relevance by favoring topics ranked by AHRQ as significant patient safety issues, the MPSMS also seeks out topics based on feedback from other federal agencies as potentially significant. One topic, angiographic adverse events, was initially considered since incorporation in MPSMS represents an opportunity to identify the rate of adverse events associated with the introduction of an emerging technology, postangiographic hemostatic devices. After being alerted to this potential growing patient safety concern by TEP members in the FDA, the MPSMS team chose this topic in an effort to be proactive in the field of patient safety surveillance. When considered with the established patient safety topic of contrast-induced renal failure, angiographic associated adverse events met our threshold for consideration.

Finally, the MPSMS team also considers topics for inclusion that have a unique relevance to CMS (e.g., adverse events associated with hip/knee replacements and postoperative pneumonia). Hip/knee replacements account for 8.5 percent of major surgical procedures in the Medicare population—double that of the next largest category, open heart procedures. This volume of major surgical

cases within our population makes this orthopedic topic inherently relevant for CMS. Our second topic not rated by AHRQ, postoperative pneumonia, is the second most frequent postoperative complication after major surgery.[7] This provides an excellent opportunity to highlight the MPSMS rationale for topic exclusion. While we are examining the second most frequent postoperative complication, the first and most frequent, postoperative wound infection, was not selected as a topic because it represents a unique inpatient surveillance challenge—a challenge that highlights some advantages and limitations of our primary data source, the inpatient medical record. The trend toward shorter acute care postoperative stays has shifted the diagnostic location for a large percentage of postoperative wound infections out of the inpatient setting. A significant extent of surgical site infection documentation is absent within the inpatient record. Without reliable proxies for this event in the administrative claims, our ability to identify postoperative wound infection is limited to early infection (occurring during inpatient convalescence) and very severe infections (those that require readmission and/or return to the operating room). Alternatively, the typical clinical history and diagnosis of postoperative pneumonia makes surveillance through inpatient record review more reliable, given the recent emphasis on early postoperative discharge (the typical SSI manifests between 7–10 days, whereas postoperative pneumonia is typically discovered in postoperative days 3–7).

The criteria used to select the adverse medical event categories were developed by the MPSMS team and include a preference for topics deemed relevant by the DHHS patient safety lead agency AHRQ. Beyond that, additional criteria were developed based on a careful review of the patient safety literature. It was believed that these criteria would identify those events that would yield both common adverse medical events and hospital processes of care. Thus, the five criteria for selecting adverse medical events were—

- the adverse event can be found. The adverse event occurrence or the occurrence, of an event considered as a proxy for an adverse event, is likely to be documented in a characteristic fashion and location(s) in the medical record.

- the adverse event is likely to be associated with exposure to a specific process of care.

- the adverse event is common. Even if a common exposure results in many adverse events, the MPSMS measures only a particular common adverse event associated with the exposure.

- the adverse event is responsible for serious morbidity/mortality.

- the adverse event is preventable or repairable. Processes can be developed or improved to prevent or decrease the morbidity resulting from the adverse event.

For abstraction efficiency at the CDACs, elements common to multiple topics are integrated within the software tool. This grouping of common elements at the CDACs is to incorporate a topic into the CDAC MPSMS workflow as a whole.

All required components necessary to make an adverse event determination are maintained as discrete, self-contained modules. Modularity provides for easy dissemination of the MPSMS methods beyond the CMS Quality Improvement Program. A health care services entity may use any of the MPSMS production topic modules for their own internal patient safety review. Central venous catheters, for example, apply it to a large chart-based data source, and identify an adverse event rate for that topic. The explicit review design provides portability to other health care systems that implicit review can not.

## Transparency

The third requirement axis is transparency. At the MPSMS, we accept the absolute need for transparency in a patient safety surveillance system. Transparency is the antithesis of the most insidious feature of our current health care culture: secrecy. The patient safety literature is replete with studies that demonstrate that the current culture of health care delivery remains a potential barrier to improving the safety of our health care delivery systems.[8–10]

That culture of secrecy is, in part, reinforced by the absence of a robust, standardized health data interchange, taxonomy, and medical knowledge representation.[2] Ironically, resting at the center of this problem is the medical record. Providers have compiled the medical record, our primary data source, which has remained largely unchanged for the past 50 years. The highly specialized, technical nature of that documentation, at times illegible and often punctuated with acronyms and eponyms, has actually created a barrier to the standardized, measured assessment of a core requirement of health care systems—namely, "do no harm." In the context of a patient safety surveillance system, the medical record barrier is actually twofold, presenting two challenges—indexing and analysis. Chart-based patient safety reviews are done by employing clinical experts for both record-indexing and analysis. This implicit review process cultivates the perception that health care delivery remains a closed society, opaque even to external review for issues of quality and safety.[3, 11]

At the MPSMS, we dissociate the indexing of the chart (performed by CDAC abstractors) from the analysis for adverse events using the algorithms. But for the MPSMS, the concept of transparency extends beyond the application of an explicit algorithmic definition to a data source of potential adverse events. Our current design provides an opportunity for total disclosure of our processes. So, in the context of transparency, it is important to address the qualitative and quantitative value of our approach, namely, the perceived value to the public, the reliability of our abstraction process, and a comparative analysis of the cost-per-chart reviewed.

As mentioned above, by fully defining the properties of selected adverse events, the MPSMS has been able to dissociate indexing from analysis and create an explicit review process that is inherently more transparent than the previous reporting systems. Some of those systems, such as the Harvard Medical Practice Review,[3] are relatively transparent because they used standardized reviewer training and broad definitions to clarify how their clinicians were guided to the

decisions to identify adverse events. Even with this approach, any implicit review project has a significant level of opacity to external review. They each have a tacit analysis element that is predominantly the prerogative of an individual physician or nurse reviewer. Health care is ill-served if adverse event determination is perceived to be only the purview of expert clinicians.[12] But explicit review has value beyond the question of public perception. As both Donabedian[13] and Hiatt[14] note, determinations made by applying explicit criteria are inherently more reliable.

In addition to improved inter-rater reliability, the MPSMS is cost effective when compared with implicit review projects. For purposes of this comparison, we are only considering the average cost-per-chart, excluding infrastructure costs that will not be incurred by health care systems seeking to use any of the MPSMS modules. These include costs associated with our technical expert panels; algorithm testing; software development; and chart copying and shipping. While these MPSMS infrastructure costs are significant, the goal of this cost comparison is to present the MPSMS explicit-review standard as an alternative for health care providers and payers. Our expectation is not to provide a comparative estimate for providers and payors, reproducing the MPSMS infrastructure. Rather, the analysis provides a benchmark to providers and payors who might use an MPSMS topic module to estimate their own adverse event rates, given a large chart data source. As described earlier, each MPSMS topic is maintained as a discrete, self-contained, portable unit. This portability will extend to all critical components of our process, including algorithms, definitions, and training tools. Our expectation is that the MPSMS standard for a topic, which can be considered an explicit adverse event definition, will be exported and applied beyond our current Medicare fee-for-service population.

We calculated our implicit review average cost-per-chart using data obtained through the clinical review arm of MPSMS algorithm development process. Because the MPSMS beta clinical review is implicit, we are able to compare per chart costs with the costs for each production chart reviewed at the CDAC. On that basis we have found that implicit clinical review has an average cost-per-chart of $350 and the MPSMS production sample average cost-per-chart is $74. The efficiencies generated due to CDAC abstractor experience and the combining of common abstracted elements in the production sample did not make for a fair average cost-per-chart per topic comparison. That said, we should report that in the MPSMS production sample we are examining charts for eight topics (bloodstream infections; central venous catheters [CVC]; total hip and total knee replacement; postoperative pneumonia, postoperative venous thromboembolic events; postoperative urinary tract infection; and ventilator associated pneumonia), while in the implicit review arm, charts were examined for no more than two adverse event topics.

# Conclusion

The Medicare Patient Safety Monitoring System is a national surveillance program designed to identify the rates of selected adverse events within the Medicare population. Our approach employs explicit, rule-based chart review to count events. The intent of this work is to provide a tool to measure the safety of hospital care delivery systems. While the MPSMS has no capacity to intervene in those systems, our design assumes that the leverage point for improvement interventions is fault tolerance, not error reduction. To that end, we have no measures of individual provider performance or provider error. By embracing a patient-centered approach, our purpose and resources mitigate the collection of comorbid risk factors for each measure. Robust comorbid risk stratification, useful for provider comparison, is resource-intensive and of little use in a system with maximal resolution at the State level. The MPSMS maintains relevance by choosing topics based on an overarching agenda to improve the safety of our nation's hospitals. Thus, our choice of topics is heavily weighted to the issues that provide the greatest public health benefit.

The public benefit would be diminished if our methods did not wholly conform to a standard of transparency from topic selection through results reporting. This transparency is a natural extension of our decision to deviate from other large patient safety surveillance projects and employ explicit review. The return on this decision is high inter-rater reliability and a lower cost-per-chart reviewed than implicit review systems.

The MPSMS, created by the DHHS Patient Safety Task Force (PSTF), is a direct byproduct of the 2000 IOM report, *To Err Is Human: Building a Safer Health System.*[1] Inherent in the mission of the PSTF—and, by extension, CMS—is a duty to understand the magnitude of patient adverse events in our nation. The dual fiduciary duties of protecting the Medicare Trust Fund and improving the safety of the health care systems, affords CMS access to the breadth and depth of information necessary to perform the tasks central to the goal of the MPSMS.

As to the MPSMS, our mandate from the DHHS, our unparalleled access to chart-level information, and our goal of keeping the patient at the center of our work, all require that this opportunity to assess the safety of our nation's health care delivery systems reaches beyond the limitations of identifying provider error by implicit review. In the MPSMS, we have changed the patient safety assessment paradigm to employ explicit review to identify patient harm. But even that unique singularity of purpose must be governed by requirements that meet both the spirit of the IOM call for a new era in patient safety and federal programmatic practicability. By declaring and maintaining our position relative to the three requirement planes of intent, relevance, and transparency, the MPSMS meets both governing principles.

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